When you apply for a Certificate of Confidentiality through the NIH website:

Identify the appropriate agency for your application: <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm>

If your study is under the authority of the Food and Drug Administration (operating under IND or IDE) there are different contacts and different instructions. **Do not continue with these instructions.**

https://humansubjects.nih.gov/coc/apply

\*Create a new Gmail address to use for this site application as it requests a google ID – I suggest nameCHLA@gmail.com

**Below are the questions asked on the Online Application**

***It may be helpful to fill this out before going to the site***

***Once in the application site you will need: Your IRB approval letter (contingent upon CoC), your consent form with CoC language in it, and your signed assurance letter (by Jodi Ogden Rivera). You should send the assurance letter for signature to the HSPP office (hspp@chla.usc.edu). It will be reviewed and sent to Jodi Ogden Rivera for signature.***

INSTITUTION INFORMATION

This is the institution with which the applicant (principal investigator) is affiliated and the recipient of funding for the research, if there is any. The principal investigator must be a faculty member of this institution. Individuals who are in a temporary status such as graduate students or post-doctoral fellows may only be listed as co-investigators in this application.

**Institution Name: Children's Hospital of Los Angeles**

Name and Title of Institutional Official

**Jodi S. Ogden Rivera, MBA, CRA** | Vice President, Research Operations

The Saban Research Institute

Children’s Hospital Los Angeles

4650 Sunset Blvd., #84 | Los Angeles, CA 90027

o: 323-361-4661 | c: 323-573-2721| jogden@chla.usc.edu

**Country: United States**

2. RESEARCH SITES List the primary site where the research will be conducted and a brief description of the facilities available for the conduct of the research. The lead site of a multi-site project should apply for a single Certificate to protect participants enrolled at all sites and should maintain a current listing of other sites.

Primary Site

**Example…Children’s Hospital of Los Angeles, 4650 Sunset Blvd. Los Angeles, CA 90027 \*example: Patients will be seen by Dr. XXXX in the XXXX department and research will continue at the CTU - see description.**

Brief Description of Facilities

**Example: Our Clinical Trials Unit (CTU) is located on the first floor in the main hospital building, in a 1625 square foot outpatient facility, alongside the Children’s Health Imaging Research Program, with four dedicated patient care areas for research participant evaluations and interventions, as well as a research laboratory for specimen processing.**

3 RESEARCH PROJECT TITLE

Please enter the title of the research project in the box below. If the project title on the IRB form (see item 5 below) is different from title given here, the applicant must document that the IRB approval pertains to this project. Include all alternate titles in addition to the IRB approved title. Alternate titles may be listed on the consent form, award letters, collaborative agreements, clinical trials registry listing, etc. When entering the titles below, put "also known as" between them.

Title(s):

**xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx**

4. SOURCE OF PROJECT FUNDING SUPPORT

Is the research funded by NIH - YES or NO, Internal Institutional funding, Other DHHS agency, Other Federal agency, State or local government funding, Foundation or non-profit organization, **Other Source List it - xxxxxxxxxx Sciences, Inc.**

5. a HUMAN SUBJECTS PROTECTION REQUIREMENTS

A Certificate of Confidentiality will not be issued to an applicant unless the project has IRB approval. The approving IRB must be in compliance with applicable Federal requirements. If the applicant institution is receiving DHHS funding for research involving human subjects, an OHRP-approved IRB for that institution must approve the project for which a Certificate of Confidentiality is sought. For additional information on OHRP and IRB assurances, see http://www.hhs.gov/ohrp/assurances/

If the applicant institution has not received DHHS funding for this research but has an IRB that complies with the requirements for IRBs imposed by another Federal agency, that IRB must approve the research. If the applicant institution does not have an IRB, the project should be reviewed by an IRB in accordance with 45 CFR Part 46.

5. b IRB APPROVAL

Attach letter or form signed by an authorized IRB representative. Approval must be current and unconditional, or **conditioned only upon the issuance of a Certificate of Confidentiality**. If this is a multi-site project, only the lead site IRB approval needs to be submitted, but the lead site must maintain copies of the IRB approval from each site, to be made available to the NIH upon request.

**Name Of IRB: Children’s Hospital of Los Angeles IRB**

**Letter of Approval: Attach it**

5. c FEDERALWIDE ASSURANCE (FWA) NUMBER/STATEMENT OF QUALIFICATIONS

Submit for the IRB that reviewed the project, the federal wide assurance (FWA) number assigned by OHRP or a statement of qualifications that the IRB complies with the applicable Federal regulations governing research involving human subjects. If this is a multi-site project, only the FWA from the lead site IRB is required.

**FWA Number: FWA00001914 expires 5/22/2020**

6. APPLICANT/PRINCIPAL INVESTIGATOR INFORMATION

Please provide the work information for the applicant/principal investigator (PI) as well as name and title of other key personnel. Also include a brief summary of the scientific training of the PI and key personnel. If this is a multi-site project, only information for PI of the lead site should be submitted to the NIH. However, the lead site must collect and maintain this information from each site. Also, you may add an email address for an alternate contact person for this application (such as the PI's administrative assistant or research coordinator).

If there are multiple co-investigators, they can be added using the "Enter More Key Personnel" button. If any of these additional investigators are co-principal investigators, this should be noted in the summary of scientific training box. Alternatively, a listing of key personnel can be uploaded and the additional co-principal investigators can be noted in that document.

Briefly, in no more than 2 or 3 sentences, state the qualifications of the Principal Investigator and note the PI's faculty affiliation with the submitting institution.

**Example of Summary of Scientific Training**

**- PhD received from Green University in Clinical Psychology in 1978**

**- Academic Faculty full time at Orange University from 1981 until present**

**Applicant Title: Dr.**

**First Name: XXXXXXXXXX**

**Last Name: XXXXXXXXXX**

**Organizational Title: Professor of Pediatrics**

**Address 1: Children's Hospital of Los Angeles**

**Address 2: 4650 Sunset Blvd. MS #XX**

**City: Los Angeles**

**State: CALIFORNIA**

**Postal Code: 90027**

**Country: United States**

**Telephone: (323) XXXXXXX**

**Fax:**

**Email: XXXX@chla.usc.edu**

**Alternate Email:**

**Summary of Scientific Training:**

**EXAMPLE - Medical College, CITY, STATE, MD, 19XX –**

**CA medical license certificate A#12345**

Key Personnel

If you have more than one key person to add, either add them individually by selecting the Enter More Key Personnel button or by uploading a document containing a list of the key personnel by selecting the Browse button. If you intend to add more than 20 key personnel, you must upload a document.

**Document Containing All Key Personnel: attach Key.docx**

7. PROJECT DATE RANGE

Please enter the date the project began or will begin and the date the project is expected to end; these will be used to set the start and expiration dates on your Certificate. If the research will not be completed by the expected end date, the Applicant must contact the NIH Certificate Coordinator about extending the protection; this should be done three months prior to the end date.

Example; (5 YEARS IF UNKNOWN)

**Beginning Date 12/01/2016**

**End Date 11/30/2021**

8. DESCRIPTION OF STUDY PROJECT AIMS AND RESEARCH METHODS

This section should include a description of the project as well as a 2 or 3 sentence brief summary of the project which will be included in the Certificate. If significant changes are made to the project aims or methods after a Certificate has been issued the Applicant should contact the NIH Certificate Coordinator to determine if the Certificate can be modified or if the Applicant will need to submit an amendment application.

*Example of Description of Study:*

*The proposed study will investigate the occurrence of maternal depression, parenting attitudes and social support, and the effects of these on infant developmental risk in a group of rural, Native American mothers. The study also examines the detrimental effects of poverty and environmental deprivation on children as mediated through mothers' psychological and social well-being and parenting behavior in the early years. In addition, the proposed study would determine prevalence rates of infant cognitive and developmental delay at one year as a developmental outcome measure. Finally, the study will look at social support as a powerful moderator of maternal psychological functioning, and a buffer to risk for children.*

*The study has four main objectives*

*1. To determine the relatedness of maternal depressive symptoms to maternal prenatal risk behaviors, i.e., smoking, alcohol and drug abuse during pregnancy.*

*2. To determine the occurrence and relatedness of maternal depressive symptoms and poor parenting attitudes at infant age 2 days, 2 months, and at 1 year in this population.*

*3. To discover maternal perceptions of social support (extended family and partner), and test the hypothesis that social support alleviates maternal depressive symptoms and poor parenting attitudes.*

*4. To test the hypothesis that infant developmental delay at 1 year is related to maternal depressive symptoms and attitudes, moderated by social support.*

*Example of Brief Summary:*

*This behavioral research study examines the relationship between maternal depressive symptoms, pre-natal risk behavior, perceived social support, and infant outcomes. Approximately 200 Native American mother-infant pairs will be recruited as subjects and evaluated at baseline and scheduled intervals for one year.*

**Description of Study – There is a word limit!!! ~215 words**

**Brief Summary – There is a word limit!!! ~65 words**

9. MEANS USED TO PROTECT SUBJECTS’ IDENTITIES

Describe the procedures used for collection and storage of personally identifiable information.

For Example: Subjects are coded by numbers not names, linking information is kept in locked files, identifiers will be destroyed when the study is completed, etc.

**Means Used**

**Example - Subjects are coded by numbers not names, linking information is kept in locked files, identifiers will be destroyed when the study is completed.**

10. REASONS FOR REQUESTING A CERTIFICATE OF CONFIDENTIALITY

Include a brief description of sensitive and identifying information to be collected.

Examples for Reason for Requesting Certificate of Confidentiality:

Sensitive information regarding drug and alcohol use, physical habits and dream content are being collected. Genetic material is being collected in patients and their families who may be at risk of developing specified diseases. Genome analysis will be performed to search for familial, disease-influencing genes and their alleles. This information, if disclosed, could expose subjects or their families to adverse economic, legal, psychological or social consequences

Reason for Request

**Example: Sensitive information regarding HIV/HEPATITIS status as well as quality of life surveys are being collected. This information, if disclosed, could expose subjects or their families to adverse economic, legal, psychological or social consequences**

11. INFORMED CONSENT FORM(S) FOR HUMAN SUBJECTS, AS IT WILL READ IF THE CERTIFICATE OF CONFIDENTIALITY IS ISSUED (ATTACH COPY)

The informed consent form must include an accurate description of the protections and limitations of the Certificate of Confidentiality, including the circumstances in which the investigators plan to voluntarily disclose identifying information about research participants (e.g., child abuse, harm to self or others, etc.).

Researchers may adapt the sample language below to the needs of their research participants and the subject matter of their study. However, the consent must cover the basic points about Certificates of Confidentiality (CoC) noted below. Researchers should also review any institutional “boilerplate” language about confidentiality and data security often included in consent forms to be certain that it is consistent with the protections of the CoC. Please contact the NIH IC CoC Coordinator if you have any questions about your consent language. \*Sample language can be viewed here –see link on website.

The researchers must also include language regarding circumstances that could lead to voluntary disclosure to authorities and appropriate professionals, without consent of the participant, such as information about child abuse, intent to hurt self or others, or other disclosures (including a description of the circumstances under which disclosures would be made).

If this is a multi-site project, only submit the consent form used by the lead site. The lead site must maintain copies of the IRB-approved consent form(s) from each participating site and must ensure that informed consent form for each site contains appropriate language about the protections and limitations (voluntary disclosures) of the Certificate of Confidentiality.

If a study uses several consent forms (e.g. a consent form and an assent form), please merge them into a single document prior to uploading.

If significant changes are made to the informed consent form after the Certificate has been issued, the Applicant should contact the Certificate Coordinator to determine if a revised consent form should be submitted to NIH.

Information for research projects with children: A Certificate of Confidentiality cannot be used to refuse to disclose identifiable research information about a minor if a parent or legal guardian requests it. The researchers may use other basis for a refusal to disclose information - after checking with their IRB about waivers of parental permission and other issues. In any case, researchers should discuss this possibility with their institution's officials.

Researchers may contact the Certificate Coordinator at the NIH IC for which they are applying with questions or additional recommendations and suggestions on language to be included in consent and assent forms regarding the Certificate of Confidentiality. (IC Contacts)

**Informed Consent Form(s): Attach 1 merged document**

12. ADMINISTRATION OF DRUGS IN RESEARCH NOT FUNDED BY NIH

Research **not** funded by NIH in which drugs will be administered to human subjects must provide the following additional information: Identification of drugs to be administered; e.g. Phenobarbital

Description of methods for administration of these drugs, including a statement of dosages; e.g. 50 to 100 mg 2 to 3 times daily. Evidence that individuals who will receive the drugs are authorized to do so under applicable Federal and State law. e.g. Patients with Alzheimer's are allowed to use anti-epileptic medications in the State of Rhode Island.

DRUG 1

Examples if Industry study

**Description of Identification of Drug**

**Tenofovir Alafenamide (TAF) IND #115561 IND holder Gilead Sciences Inc.**

**Description of Administration of Drug**

**Subjects randomly assigned (2:1) to receive one of the following treatments- blinded: ArmA:TAF 25mgQD - ArmB: Placebo to Match TAF 25mgQD. Double-blinded phase is 24wks, followed by open-label extension phase of 216 wks. Total duration 240 weeks.**

Evidence of Authorization

The following is evidence that individuals who will receive the drugs are authorized to do so under applicable Federal and State law: **Children's Hospital Los Angeles Pharmacy, California State Board of Pharmacy Hospital Pharmacy Permit #HSP 13726 - Dr. xxxx. xxxxx's CA Med License A#12345**

13. ALL RESEARCH IN WHICH A CONTROLLED DRUG OR DRUGS WILL BE ADMINISTERED (ATTACH COPY)

All research in which a controlled drug or drugs will be administered must upload a copy of the Drug Enforcement Administration Certificate of Registration (DEA Form 223) under which the research project will be conducted.

**This section is not applicable (n/a) to your application – unless controlled substance**

14. RESEARCH PROJECT PLANS FOR REPORTING COMMUNICABLE DISEASES

If the research project is testing for reportable communicable diseases, the applicant must submit information relating to its plans for working with State and local authorities as specified in the August 9, 1991 memorandum from the Assistant Secretary for Health (http://grants.nih.gov/grants/policy/coc/cd\_policy.htm).

**Plans for Reporting Communicable Diseases**

**Write this: The PI will abide by state and local authority regulations, and uphold the law according to the Los Angeles County Department of Public Health, Reportable Diseases and Conditions, Title 17, California Code of Regulations as well as the Children’s Hospital of Los Angeles Policies and Procedures; ADM-112: HIV Testing and Reporting, and IC-205: Communicable Disease Reporting.**

15. ASSURANCES

This institution agrees to use the Certificate of Confidentiality to protect against disclosure of personally identifiable information and to support and defend the authority of the Certificate. Specifically, any investigator or institution conducting research protected by a Certificate of Confidentiality SHALL NOT, without the specific consent of the individual to who the information pertains:

• Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research; or

• Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure of protected information is permitted only when:

• Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

• Made with the consent of the individual to whom the information, document, or biospecimen pertain, including disclosure necessary for an individual’s medical treatment; or

• Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research

The institution understands that research information protected by a Certificate of Confidentiality and all copies thereof are protected in perpetuity and are subject to the protections and the disclosure requirements noted above.

The institution understands that identifiable, sensitive information protected by the Certificate of Confidentiality and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suite, or other judicial, legislative, or administrative proceeding.

The institution and personnel involved in the conduct of the research will comply with the informed consent requirements of the applicable Federal regulations, including 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the HHS or NIH or used to coerce individuals to participate in the research project.

For studies in which informed consent is sought, subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate. Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

**Scanned signed assurance form: attach it – Template provided**